February 23, 2005

HOUSE BILL No. 1441

DIGEST OF HB 1441 (Updated February 22, 2005 6:07 pm - DI 77)

Citations Affected: IC 12-15; noncode.

Synopsis: Medicaid prescription drug coverage. Allows the office of Medicaid policy and planning to provide a prescription drug benefit in the Medicaid risk based managed care program. Allows a managed care provider contract or provider agreement to include a prescription drug program.

Effective: July 1, 2005.

Brown T, Becker

January 18, 2005, read first time and referred to Committee on Public Health.
February 22, 2005, amended, reported — Do Pass.

February 23, 2005

First Regular Session 114th General Assembly (2005)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2004 Regular Session of the General Assembly.

HOUSE BILL No. 1441

A BILL FOR AN ACT to amend the Indiana Code concerning Medicaid.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 12-15-5-5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 5. **(a) The office may provide a prescription drug benefit to a Medicaid recipient in the Medicaid risk based managed care program.**

(b) If the office provides a prescription drug benefit to a Medicaid recipient in the Medicaid risk based managed care program, the provisions of IC 12-15-35.5 apply.

(c) If the office does not provide a prescription drug benefit to a Medicaid recipient in the Medicaid risk based managed care program, a Medicaid managed care organization ~~that provides~~ **shall provide** coverage and reimbursement for outpatient single source legend drugs ~~is~~ subject to IC 12-15-35-46 and IC 12-15-35-47.

SECTION 2. IC 12-15-12-4.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 4.5. A managed care provider's contract or provider agreement with the office may include a prescription drug program, subject to IC 12-15-5-5, IC 12-15-35,**

and IC 12-15-35.5.

SECTION 3. IC 12-15-35-28, AS AMENDED BY P.L.28-2004, SECTION 104, AND AS AMENDED BY P.L.97-2004, SECTION 51, IS CORRECTED AND AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 28. (a) The board has the following duties:

(1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.

(2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.

(3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.

(4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.

(5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year. The report *issued* to the legislative council must be in an electronic format under IC 5-14-6.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR

program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under ~~410 IAC 16.2-3-8~~ **410 IAC 16.2-3.1** and 42 CFR 483.60.

(11) The research, development, and approval of a preferred drug list for:

(A) Medicaid's fee for service program;

(B) Medicaid's primary care case management program; ~~and~~

(C) Medicaid's risk based managed care program, if the office provides a prescription drug benefit and subject to IC 12-15-5; and

~~(C)~~ **(D)** ~~the primary care case management component of~~ the children's health insurance program under IC 12-17.6;

in consultation with the therapeutics committee.

(12) The approval of the review and maintenance of the preferred drug list at least two (2) times per year.

(13) The preparation and submission of a report concerning the preferred drug list at least two (2) times per year to the select joint commission on Medicaid oversight established by IC 2-5-26-3.

(14) The collection of data reflecting prescribing patterns related to treatment of children diagnosed with attention deficit disorder

or attention deficit hyperactivity disorder.

(15) Advising the Indiana comprehensive health insurance association established by IC 27-8-10-2.1 concerning implementation of chronic disease management and pharmaceutical management programs under IC 27-8-10-3.5.

(b) The board shall use the clinical expertise of the therapeutics committee in developing a preferred drug list. The board shall also consider expert testimony in the development of a preferred drug list.

(c) In researching and developing a preferred drug list under subsection (a)(11), the board shall do the following:

(1) Use literature abstracting technology.

(2) Use commonly accepted guidance principles of disease management.

(3) Develop therapeutic classifications for the preferred drug list.

(4) Give primary consideration to the clinical efficacy or appropriateness of a particular drug in treating a specific medical condition.

(5) Include in any cost effectiveness considerations the cost implications of other components of the state's Medicaid program and other state funded programs.

(d) Prior authorization is required for coverage under a program described in subsection (a)(11) of a drug that is not included on the preferred drug list.

(e) The board shall determine whether to include a single source covered outpatient drug that is newly approved by the federal Food and Drug Administration on the preferred drug list not later than sixty (60) days after the date on which the manufacturer notifies the board in writing of the drug's approval. However, if the board determines that there is inadequate information about the drug available to the board to make a determination, the board may have an additional sixty (60) days to make a determination from the date that the board receives adequate information to perform the board's review. Prior authorization may not be automatically required for a single source drug that is newly approved by the federal Food and Drug Administration, and that is:

(1) in a therapeutic classification:

(A) that has not been reviewed by the board; and

(B) for which prior authorization is not required; or

(2) the sole drug in a new therapeutic classification that has not been reviewed by the board.

(f) The board may not exclude a drug from the preferred drug list based solely on price.

(g) The following requirements apply to a preferred drug list

developed under subsection (a)(11):

(1) Except as provided by IC 12-15-35.5-3(b) and IC 12-15-35.5-3(c), the office or the board may require prior authorization for a drug that is included on the preferred drug list under the following circumstances:

(A) To override a prospective drug utilization review alert.

(B) To permit reimbursement for a medically necessary brand name drug that is subject to generic substitution under IC 16-42-22-10.

(C) To prevent fraud, abuse, waste, overutilization, or inappropriate utilization.

(D) To permit implementation of a disease management program.

(E) To implement other initiatives permitted by state or federal law.

(2) All drugs described in IC 12-15-35.5-3(b) must be included on the preferred drug list.

(3) The office may add a drug that has been approved by the federal Food and Drug Administration to the preferred drug list without prior approval from the board.

(4) The board may add a drug that has been approved by the federal Food and Drug Administration to the preferred drug list.

(h) At least two (2) times each year, the board shall provide a report to the select joint commission on Medicaid oversight established by IC 2-5-26-3. The report must contain the following information:

(1) The cost of administering the preferred drug list.

(2) Any increase in Medicaid physician, laboratory, or hospital costs or in other state funded programs as a result of the preferred drug list.

(3) The impact of the preferred drug list on the ability of a Medicaid recipient to obtain prescription drugs.

(4) The number of times prior authorization was requested, and the number of times prior authorization was:

(A) approved; and

(B) disapproved.

(i) The board shall provide the first report required under subsection (h) not later than six (6) months after the board submits an initial preferred drug list to the office.

SECTION 4. IC 12-15-35-45 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 45. (a) The chairman of the board, subject to the approval of the board members, may appoint an advisory committee to make recommendations to the board

on the development of a Medicaid outpatient drug formulary.

(b) If the office decides to establish a Medicaid outpatient drug formulary, the formulary shall be developed by the board.

(c) A formulary, **preferred drug list, or prescription drug benefit** used by a Medicaid managed care organization is subject to **IC 12-15-5-5 and** sections 46 and 47 of this chapter.

SECTION 5. IC 12-15-35.5-1 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 1. ~~(a) Except as provided in subsection (b),~~ This chapter applies to:

(1) the Medicaid program under this article; and

(2) the children's health insurance program under IC 12-17.6.

~~(b) This chapter does not apply to a formulary or prior authorization program operated by a managed care organization under a program described in subsection (a).~~

SECTION 6. IC 12-15-35.5-3 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 3. (a) Except as provided in subsection (b), the office may establish prior authorization requirements for drugs covered under a program described in ~~section 1(a)~~ **section 1** of this chapter.

(b) The office may not require prior authorization for the following single source or brand name multisource drugs:

(1) A drug that is classified as an antianxiety, antidepressant, or antipsychotic central nervous system drug in the most recent publication of Drug Facts and Comparisons (published by the Facts and Comparisons Division of J.B. Lippincott Company).

(2) A drug that, according to:

(A) the American Psychiatric Press Textbook of Psychopharmacy;

(B) Current Clinical Strategies for Psychiatry;

(C) Drug Facts and Comparisons; or

(D) a publication with a focus and content similar to the publications described in clauses (A) through (C);

is a cross-indicated drug for a central nervous system drug classification described in subdivision (1).

(3) A drug that is:

(A) classified in a central nervous system drug category or classification (according to Drug Facts and Comparisons) that is created after the effective date of this chapter; and

(B) prescribed for the treatment of a mental illness (as defined in the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

(c) Except as provided under section 7 of this chapter, a recipient enrolled in a program described in ~~section 1(a)~~ **section 1** of this chapter shall have unrestricted access to a drug described in subsection (b).

SECTION 7. [EFFECTIVE JULY 1, 2005] **(a) As used in this SECTION, "managed care provider" refers to a managed care organization that has entered into a contract with the office to provide services under Medicaid's risk based managed care program.**

(b) As used in this SECTION, "office" refers to the office of Medicaid policy and planning established by IC 12-8-6-1.

(c) IC 12-15-12-4.5, as added by this act, applies to a provider agreement or contract entered into, amended, or renewed after June 30, 2005, between the office and a managed care provider.

(d) This SECTION expires December 31, 2010.

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1441, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 1, line 2, after "(a)" insert "**The office may provide a prescription drug benefit to a Medicaid recipient in the Medicaid risk based managed care program.**

(b) If the office provides a prescription drug benefit to a Medicaid recipient in the Medicaid risk based managed care program, the provisions of IC 12-15-35.5 apply.

(c) If the office does not provide a prescription drug benefit to a Medicaid recipient in the Medicaid risk based managed care program,".

Page 1, line 2, delete "A" and insert "a".

Page 1, line 3, after "provides" insert "**shall provide**".

Page 1, line 3, reset in roman "coverage and reimbursement".

Page 1, line 4, reset in roman "for outpatient single source legend drugs".

Page 1, line 4, reset in roman "subject to IC 12-15-35-46".

Page 1, line 5, reset in roman "and IC 12-15-35-47.".

Page 1, line 5, delete "may not provide prescription drug coverage".

Page 1, delete lines 6 through 9.

Page 1, line 13, delete "not".

Page 1, line 14, delete "program." and insert "**program, subject to IC 12-15-5-5, IC 12-15-35, and IC 12-15-35.5.**".

Page 3, line 26, delete "program;" and insert "**program, if the office provides a prescription drug benefit and subject to IC 12-15-5;**".

Page 5, line 40, reset in roman "(c) A".

Page 5, line 40, delete "formulary" and insert "formulary,".

Page 5, line 40, before "used" insert "**preferred drug list, or prescription drug benefit**".

Page 5, line 40, reset in roman "used by a Medicaid managed care organization is".

Page 5, line 41, reset in roman "subject to".

Page 5, line 41, before "sections" insert "**IC 12-15-5-5 and**".

Page 5, line 41, reset in roman "sections 46 and 47 of this chapter.".

Page 6, delete lines 39 through 41.

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1441 as introduced.)

BECKER, Chair

Committee Vote: yeas 9, nays 0.